

Validation of a Method for the Determination of Acetonitrile in Human Exhalate Using Thermal Desorption with GC-NPD

Sample Identification	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
LLOQ QC 7.50µg/mL	1	5.92	7.50	78.9	80.9	4.74	5.86	V8
	2	5.43	7.50	72.4				
	3	6.23	7.50	83.1				
	4	6.30	7.50	84.0				
	5	6.11	7.50	81.5				
	6	6.41	7.50	85.5				
Low QC 15.0µg/mL	1	13.8	15.0	92.0	93.9	4.83	5.14	V12
	2	13.1	15.0	87.3				
	3	14.2	15.0	94.7				
	4	13.7	15.0	91.3				
	5	14.6	15.0	97.3				
	6	15.1	15.0	101				
Medium QC 30.0µg/mL	1	23.6	30.0	78.7	89.9	7.25	8.06	V12
	2	27.1	30.0	90.3				
	3	26.2	30.0	87.3				
	4	26.5	30.0	88.3				
	5	30.1	30.0	100				
	6	28.5	30.0	95.0				
High QC 60.0µg/mL	1	51.1	60.0	85.2	89.2	4.54	5.09	V12
	2	51.5	60.0	85.8				
	3	50.6	60.0	84.3				
	4	55.8	60.0	93.0				
	5	55.5	60.0	92.5				
	6	56.6	60.0	94.3				

NA Not applicable.

QC val exhalate7.5LLOQ.xls, 4level QC Val (new LLOQ)
10:12 PM 9/20/01

Analyst: _____

Reviewed by: _____

PM3006635929

Validation of a Method for the Determination of Acetonitrile in Human Exhalate Using Thermal Desorption with GC-NPD

Sample Identification	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
LLOQ QC 7.50µg/mL	1	5.92	7.50	78.9	80.9	4.74	5.86	V8
	2	5.43	7.50	72.4				
	3	6.23	7.50	83.1				
	4	6.30	7.50	84.0				
	5	6.11	7.50	81.5				
	6	6.41	7.50	85.5				
					6.07	0.354	5.83	concentrati
						0.145	a	SEE

NA Not applicable.

a SEE = STD Deviation / SQRT (# of determinations).
SEE=STANDARD ERROR OF ESTIMATE

QC val exhalate7.5LLOQ.xls, QC Val (new LLOQ)
10:12 PM 9/20/01

Analyst: _____

Reviewed by: _____

PM3006635930

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QC val exhalate7.5LLOQ.xls, QC Val (new LLOQ)
10:12 PM 9/20/01

Analyst: _____

Reviewed by: _____

PM3006635931

Validation of a Method for the Determination of Acetonitrile in Human Exhalate Using Thermal Desorption with GC-NPD

Sample Identification	Covance Log Number	Retention Time	Mean Retention Time	Standard Deviation	Relative Standard Deviation (%)	Response (Area)	Mean Area	Standard Deviation	Relative Standard Deviation (%)	Reference Page(s)
50.0µg/mL 6-0432-1C	Standard	7.07	7.10	0.016	0.225	555805	302252	147922.5	48.9	V6
50.0µg/mL 6-0432-1C	Standard	7.08				252991				V7
50.0µg/mL 6-0432-1C	Standard	7.10				127993				V8
50.0µg/mL 6-0432-1C	Standard	7.10				211013				V9
50.0µg/mL 6-0432-1C	Standard	7.11				365457				V11
50.0µg/mL 6-0432-1C	Standard	7.11				300254				V12

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Sample Identification	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
Low QC 15.0µg/mL-24/RT	1	15.4	15.0	103	102	4.6	4.51	V9
	2	14.1	15.0	94.0				
	3	15.4	15.0	103				
	4	15.7	15.0	105				
	5	14.9	15.0	99.3				
	6	16.0	15.0	107				
High QC 60.0µg/mL-24/RT	1	48.1	60.0	80.2	93.0	8.33	8.96	V9
	2	55.4	60.0	92.3				
	3	52.0	60.0	86.7				
	4	58.2	60.0	97.0				
	5	59.9	60.0	99.8				
	6	61.4	60.0	102				

NA Not applicable.

Validation of a Method for the Determination of Acetonitrile in Human Exhalate Using Thermal Desorption with GC-NPD

Sample Identification	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
Low QC 15.0µg/mL-24/REF	1	17.3	15.0	115	108	10.2	9.44	V8
	2	16.7	15.0	111				
	3	17.5	15.0	117				
	4	14.8	15.0	98.7				
	5	13.8	15.0	92.0				
	6	17.1	15.0	114				
High QC 60.0µg/mL-24/REF	1	49.7	60.0	82.8	84.4	4.97	5.89	V3
	2	47.8	60.0	79.7				
	3	46.8	60.0	78.0				
	4	53.4	60.0	89.0				
	5	52.0	60.0	86.7				
	6	54.0	60.0	90.0				

NA Not applicable.

Validation of a Method for the Determination of Acetonitrile in Human Exhale Using Thermal Desorption with GC-NPD

Sample Identification	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
LOD QC 5.00µg/mL-24/REF	1	9.30	5.00	186	183	22.1	12.1	V6
	2	10.2	5.00	204				
	3	7.99	5.00	160				
LOD QC 10.0µg/mL-24/REF	4	12.4	10.0	124	110	14.0	12.7	V6
	5	9.61	10.0	96.1				
	6	11.1	10.0	111				
LOD QC 15.0µg/mL-24/REF	1	18.0	15.0	120	112	17.4	15.5	V6
	2	13.8	15.0	92.0				
	3	18.6	15.0	124				

NA Not applicable.

Validation of a Method for the Determination of Acetonitrile in Human Exhale Using Thermal Desorption with GC-NPD

Sample Identification	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
Low QC 15.0µg/mL-F/T	1	14.2	15.0	94.7	87.5	12.1	13.8	V8
	2	15.6	15.0	104				
	3	10.4	15.0	69.3				
	4	12.6	15.0	84.0				
	5	13.8	15.0	92.0				
	6	12.1	15.0	80.7				
High QC 60.0µg/mL-F/T	1	61.5	60.0	103	103	4.5	4.37	V9
	2	63.8	60.0	106				
	3	56.3	60.0	93.8				
	4	62.7	60.0	105				
	5	62.8	60.0	105				
	6	62.1	60.0	104				

NA Not applicable.

Validation of a Method for the Determination of Acetonitrile in Human Exhalate Using Thermal Desorption with GC-NPD

Sample Identification	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
LOD QC 5.00µg/mL-F/T	1	5.89	5.00	118	111	18.9	17.0	V6
	2	6.24	5.00	125				
	3	4.47	5.00	89.4				
LOD QC 10.0µg/mL-F/T	4	8.76	10.0	87.6	95.9	10.72	11.2	V6
	5	9.21	10.0	92.1				
	6	10.8	10.0	108				
LOD QC 15.0µg/mL-F/T	1	14.6	15.0	97.3	93.5	4.02	4.30	V6
	2	14.1	15.0	94.0				
	3	13.4	15.0	89.3				

NA Not applicable.

Validation of a Method for the Determination of Acetonitrile in Human Exhale Using Thermal Desorption with GC-NPD

Sample Identification	Replicate	Concentration (µg/mL)	Concentration Added (µg/mL)	Percent Recovery (%)	Mean (%)	Standard Deviation (%)	Relative Standard Deviation (%)	Reference Page(s)
Low QC 15.0µg/mL-inj	1	13.4	15.0	89.3	89.7	0.49	0.546	V8
	2	13.5	15.0	90.0				
High QC 60.0µg/mL-inj	1	59.1	60.0	98.5	97.2	1.91	1.97	V9
	2	57.5	60.0	95.8				
0.200µg/mL 6-0432-1G-inj	1	0.421	0.200	211				V4
1.00µg/mL 6-0432-1F-inj	1	1.29	1.00	129				
5.00µg/mL 6-0432-1E-inj	1	4.66	5.00	93.2				
20.0µg/mL 6-0432-1D-inj	1	18.1	20.0	90.5				
50.0µg/mL 6-0432-1C-inj	1	44.3	50.0	88.6				
80.0µg/mL 6-0432-1B-inj	1	70.9	80.0	88.6				

NA Not applicable.

a Method for the Determination of Acetonitrile in Human Exhalate Using Thermal Desorption with GC-NP

Sample Identification	Replicate	Concentration ($\mu\text{g/mL}$)	Concentration Added ($\mu\text{g/mL}$)	Percent Recovery (%)	Reference Page(s)
1.00 $\mu\text{g/mL}$ 6-0432-3C	1	0.585	1.00	58.5	V6
20.0 $\mu\text{g/mL}$ 6-0432-3B	1	17.0	20.0	85.0	
50.0 $\mu\text{g/mL}$ 6-0432-3A	1	46.0	50.0	92.0	
1.00 $\mu\text{g/mL}$ 6-0432-4C	1	0.755	1.00	75.5	V6
20.0 $\mu\text{g/mL}$ 6-0432-4B	1	19.5	20.0	97.5	
50.0 $\mu\text{g/mL}$ 6-0432-4A	1	52.0	50.0	104	

NA Not applicable.

Analyst: _____

QC val exhalate7.5LLOQ.xls, Std Soln Stability
10:12 PM 9/20/01

Reviewed by: _____

PM3006635939

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QC val exhalate7.5LLOQ.xls, Std Soln Stability
10:12 PM 9/20/01

Analyst: _____

Reviewed by: _____

PM3006635940

Validation of a Method for the Determination of Acetonitrile in Human Exhalate Using Thermal Desorption with GC-NPD

Sample Identification	Replicate	Bag Volume (mL)	Mean (mL)	Standard Deviation (mL)	Relative Standard Deviation (%)	Reference Page(s)
Tedlar Bag	1	650	650	28.7	4.42	V10
	2	680				
	3	690				
	4	600				
	5	610				
	6	640				
	7	660				
	8	640				
	9	660				
	10	670				

QC val exhalate7.5LLOQ.xls, bag inflation Vol
10:12 PM 9/20/01

Analyst: _____

Reviewed by: _____

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